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| APPLICATION NO.   | FILING DATE          | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|----------------------|----------------------|---------------------|------------------|
| 10/699,921  | 11/03/2003           | Dennis M. Treu       | 53951-108           | 3896             |
| 21890 7590 01/23/2007<br>PROSKAUER ROSE LLP<br>PATENT DEPARTMENT<br>1585 BROADWAY |                      |                      | EXAMINER            |                  |
|   |                      |                      | WIEST, PHILIP R     |                  |
| NEW YORK, N   |                      |                      | ART UNIT            | PAPER NUMBER     |
| •   |                      |                      | 3761                |                  |
| <del></del>   |                      |                      |                     |                  |
| SHORTENED STATUTOR  | Y PERIOD OF RESPONSE | MAIL DATE            | DELIVERY MODE       |                  |
| 3 MONTHS  |                      | 01/23/2007           | PAPER               |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

|   | Application No.  | Applicant(s)  |  |  |  |  |
|---|--|---|--|--|--|--|
| ·   | 10/699,921   | TREU, DENNIS M.   |  |  |  |  |
| Office Action Summary   | Examiner   | Art Unit  |  |  |  |  |
|   | Phil Wiest   | 3761  |  |  |  |  |
| The MAILING DATE of this communication app  | ears on the cover sheet with the c   | orrespondence address   |  |  |  |  |
| Period for Reply  |  |   |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period willow to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b) | TE OF THIS COMMUNICATION 6(a). In no event, however, may a reply be tim ill apply and will expire SIX (6) MONTHS from to cause the application to become ABANDONED | l. ely filed the mailing date of this communication. 0 (35 U.S.C. § 133).   |  |  |  |  |
| Status  |  | e de la companya de<br>La companya de la co |  |  |  |  |
| 1) Responsive to communication(s) filed on 03 No  | ovember 2003.  |   |  |  |  |  |
|   | action is non-final.   |   |  |  |  |  |
| 3) Since this application is in condition for allowan   | <del>-</del>   |   |  |  |  |  |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.   |  |   |  |  |  |  |
| Disposition of Claims   |  |   |  |  |  |  |
| 4) Claim(s) 1-10 is/are pending in the application.   |  |   |  |  |  |  |
| 4a) Of the above claim(s) <u>5</u> is/are withdrawn from consideration.   |  |   |  |  |  |  |
| 5) Claim(s) is/are allowed.   |  |   |  |  |  |  |
| 6)⊠ Claim(s) <u>1-4 and 6-10</u> is/are rejected.   | · · · · · · · · · · · · · · · · · · ·  |   |  |  |  |  |
| 7) Claim(s) <b>#</b> is/are objected to.  |  |   |  |  |  |  |
| 8) Claim(s) are subject to restriction and/or   | election requirement.  |   |  |  |  |  |
| Application Papers  |  |   |  |  |  |  |
| 9) The specification is objected to by the Examiner   |  | ·   |  |  |  |  |
| 10)⊠ The drawing(s) filed on <u>11/3/03</u> is/are: a)⊠ accepted or b)⊡ objected to by the Examiner.  |  |   |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |  |   |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  |  |   |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  |  |   |  |  |  |  |
| Priority under 35 U.S.C. § 119  |  |   |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  | priority under 35 U.S.C. § 119(a)  | -(d) or (f).  |  |  |  |  |
| 1. Certified copies of the priority documents have been received.   |  |   |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No  |  |   |  |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage   |  |   |  |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).   |  |   |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.  |  |   |  |  |  |  |
|   |  | ·   |  |  |  |  |
|   |  |   |  |  |  |  |
| Attachment(s)   |  |   |  |  |  |  |
| 1) Notice of References Cited (PTO-892)   | 4) Interview Summary   |   |  |  |  |  |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08)  | Paper No(s)/Mail Da 5) Notice of Informal Pa   |   |  |  |  |  |
| Paper No(s)/Mail Date 6) Other:   |  |   |  |  |  |  |

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#### **DETAILED ACTION**

#### Election/Restrictions

1. Applicant's election of the species corresponding to Figure 1: Claims 1-4 and 6-10 in the reply filed on 11/20/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim 5 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/20/06.

### Claim Objections

Claim 10 objected to because of the following informalities: On line 4, Applicant refers to "said monitoring." It appears as though the last word of the sentence was cut off. Additionally, because data is displayed on the display device portion of the monitoring control unit, the Examiner recommends that "said monitoring" be changed to "said display device." Appropriate correction is required.

## Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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- 3. Claims 1, 3, 6, and 8-10 rejected under 35 U.S.C. 102(b) as being anticipated by Causey, III et al. (US 6,641,533)
- With respect to Claim 1, Causey, III et al. disclose a medical treatment device that can be connected to a computer (monitor unit) 6, the system comprising a treatment unit 400, a monitor unit 6, said treatment unit 400 comprising an infusion pump that delivers a medical treatment to a patient. The monitor unit 6 is capable of receiving data from the treatment unit 400 via a common control unit (200, 300) (Column 23, Lines 49-52) and outputting at least data relating to the status of the treatment being delivered on a display portion 12. Regarding the one-way transmission of data, Causey, III et al. further discloses that the computer 6 (monitoring portion) is capable of receiving data from the treatment unit 400 via a medical device module 200 for analysis (Column 23, Lines 49-52 and Figure 10), but does not disclose the computer 6 transmits data back to the medical device module 200 (as demonstrated by the one-way arrow to the communication station in Figure 10). Therefore, Causey, III et al. discloses a one-way communication channel between the treatment unit (400 by way of 200) and the monitoring device 6, such that the treatment machine 400 is not affected by a data-processing software being operated by the monitor device 6.
- 5. With respect to Claim 3, Causey, III et al. disclose that the treatment unit 400 and monitor unit 6 are connected to a common control unit (200, 300) (see Figures 7 and 10). The common control panel (200, 300) is capable of controlling and receiving data from the treatment unit 400, as well as transferring said data to the monitoring unit 6.

Because the monitoring unit 6 does not transmit data back to the common control unit (200, 300), as shown by the one-way arrow in Figure 10, any signals from the monitor unit 400 are prevented from affecting a state of the treatment unit 400.

- 6. With respect to Claim 6, Causey, III et al. disclose a medical treatment device that can be connected to a computer 6, the system comprising a treatment machine (200, 400) and monitor device 6 (see Figures 7 and 10), having a programmable processor and a memory, where the processor is capable of being programmed to control data synthesis and display responsive to software run by the programmable processor (Column 23, Lines 49-52). Regarding the one-way transmission of data, Causey, III et al. further discloses that the computer 6 (monitoring portion) is capable of receiving data from the medical device module 200 for analysis (Column 23, Lines 49-52 and Figure 10), but does not disclose the computer 6 transmits data back to the medical device module 200 (as demonstrated by the one-way arrow to the communication station in Figure 10). Therefore, Causey, III et al. discloses a one-way communication channel between the treatment machine (200, 400) and the monitoring device 6, such that the treatment machine 400 is not affected by a data-processing software being operated by the monitor device 6, and therefore is capable of operating without said monitoring device.
- 7. With respect to Claim 8, Causey, III et al. disclose that the communications channel between the may be wireless (Column 24, Lines 4-15).
- 8. With respect to Claim 9, Causey, III et al. disclose a medical treatment device comprising a blood treatment unit 400, a monitoring control 6 and display device 12, a

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control computer (200, 300) controlling said blood treatment unit 400, and a monitoring computer 14 controlling said monitoring control 6 and display device 12 (see Figures 1, 7, and 10). The monitoring computer 14 is capable of receiving information from the control computer (200, 300) for data-recording purposes (Column 23, Lines 49-52), but the it is not required that the monitoring computer 14 transmits information back to the control computer (Column 23, Lines 54-56). Therefore, failures in the monitoring computer, which only records data, will not affect the state of the control computer, which is capable of controlling the blood treatment unit 400 on its own.

9. With respect to Claim 10, the monitoring computer 14 is capable of interpreting data received from the control computer (200, 300) and displaying it on the display 12.

### Claim Rejections - 35 USC § 103

- 10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 11. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - 1. Determining the scope and contents of the prior art.
  - 2. Ascertaining the differences between the prior art and the claims at issue.
  - 3. Resolving the level of ordinary skill in the pertinent art.
  - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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12. Claims 2, 4, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Causey, III et al. in view of Gilcher et al. (US 6,113,554). Causey, III et al. teach the medical treatment devices as disclosed in Claims 1 and 6, but do not teach that the treatment unit and monitor unit are housed together in a single housing. Gilcher et al. disclose a blood collection system comprising a housing 14 that houses a monitor unit 10 and a treatment unit 12. The housing further comprises a control panel 72, as per Claim 4. It would have been obvious to one skilled in the art at the time of medical treatment device of Causey, III et al. with the unitary housing of Gilcher et al. in order to provide a simplified unit for medical treatment that does not comprise several parts. Furthermore, Causey et al. disclose that the device was broken into components in order to improve price and upgradability, and that some devices would preferably be combined into a single device. The components that comprise the medical treatment device are more than capable of functioning as a singular unit in a common housing.

### Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571) 272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PRW 1/12/07 TATYANA ZALUKAEVA SUPERVISORY PRIMARY EXAMINER Page 7